



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/160,805 12/14/99 DISCHER

EXAMINER
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HM12/0605

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ART UNIT	PAPER NUMBER
	3

DATE MAILED: 5

06/15/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirements

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

2. Claims 11-12, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**'The polymersome' and 'the copolymers' in claim 11 lack an antecedent basis in claim 1.**

**The members recited as Markush members are compounds and not compositions. Therefore, 'composition selected from the group consisting of' is improper. Furthermore, the distinction between a drug and a therapeutic compound and a steroid is unclear. Similar is the case with a nutrient and sugar, and salt and electrolyte. Sugar is a nutrient and a salt is an electrolyte. What is being conveyed by 'biosealant'? Seals what?. Similar is the case with ferrofluid?**

**What is an electroforming step as recited in claim 17?**

**It is unclear how the composition is modulated as recited in claim 18. Since this is a method claim, reciting this step is important.**

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Claim 20 is confusing. Is it a product by process claim? If so, the steps should be recited properly.

3. Claims 15 and 16 provide for the use of the polymersome, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

What is being conveyed through claim 20? Is it a product by process? If so, how the membrane is formed should be recited.

*Claim Rejections - 35 U.S.C. § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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5. Claims 1-4, 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Henselwood (Macromolecules, 1998) or Hajduk (J. Of Phys. Chem., 1998) or Ding (J. Phys. Chem., 1998) or Cornelissen (1998) or Fendler (Science, 1984) all are of record.

The above references teach polymeric vesicles having a membrane; the polymers are diblock polymers (note abstracts in each). The references meet the requirements of instant claims.

6. Claims 1-4, 6 and 9-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Hentze (Macromolecules, 1999) of record.

Hentze teaches polymeric vesicles having a membrane; the polymers are diblock polymers (note abstract). The reference meets the requirements of instant claims.

7. Claims 1-2, 7-9, and 14-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu (Macromolecules, 1999) of record.

Liu teaches polymeric vesicles having a membrane, acryloylphospholipids which are cross-linked (note abstract). The reference meets the requirements of instant claims.

*Claim Rejections - 35 U.S.C. § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was

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**made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**9. Claims 5 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding, Henselwood, Fendler or Hentze cited above.**

**The references of Ding, Henselwood, Fendler and Hentze are all suggestive of the potential applications of the polymeric vesicles for the drug delivery. The use of the polymeric systems taught by Ding, Henselwood, Fendler or Hentze for drug delivery would have been obvious to one of ordinary skill in the art since these references are suggestive of the drug delivery. The criticality of a triblock polymer is not readily apparent to the examiner since from the references it would appear that the amphophilic nature of the polymer is the determinant factor.**

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**June 4, 2001**